



**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rana et al.

Examiner: David Lukton

Application No.: 09/972,016

Group Art Unit: 1653

Filed: October 4, 2001

Docket: 1368-9 (267.302)

For:

SITE-SPECIFIC PROTEIN

Dated: April 7, 2004

**MODIFICATION** 

Confirmation No.: 2378

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Alexandria, VA 22313

Dated: April 7, 2004

Signature: Barbara Thon

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

The Examiner has required restriction under 35 U.S.C. Section 121 between one of the following groups, which the Examiner has alleged as being distinct inventions:

Group I. Claims 1-5, 20, 21, 24-25, drawn to a modified protein.

Group II. Claims 6-8, 22, 23, 26, 27, drawn to a method of producing a modified protein, which method also requires synthesis of an amino acid.

Group III. Claims 9-14 and 19, drawn to a method of modifying an existing protein, without also modifying a cysteine or lysine.

Application No.: 09/972,016

Amendment and Response dated April 7, 2004 Reply to Office Action of March 11, 2004

Docket No.: 1368-9

Page 2

Group IV. Claims 15-18, drawn to a method of determining protein/RNA interactions.

The Examiner states the following:

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05 (h)). However, in the event that Group I is elected, and claims therein found allowable, claims drawn to a method of making the modified protein will be rejoined for further examination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Additionally, the Examiner indicates that applicants are required to elect species. In particular, the Examiner states the following with respect to Group IV:

In the event that Group IV is chosen for initial examination, the first "specie" would be a specific protein that is "labeled" and which contains a donor dye molecule; the second "specie" would be a specific acceptor dye molecule.

Applicants provisionally elect Group IV, with traverse.

Applicants provisionally elect, with traverse, a Tat protein labeled with a donor dye molecule as the specific protein for Group IV. The term "protein", as defined in Applicants' specification (see page 6, lines 13-15) includes proteins, polypeptides and fragments of proteins or peptides which retain the desired biological activity of any protein of interest.

Application No.: 09/972,016

Amendment and Response dated April 7, 2004 Reply to Office Action of March 11, 2004

Docket No.: 1368-9

Page 3

Applicants provisionally elect, with traverse, a fluorophore as the specific acceptor dye molecule for Group IV.

Groups I-IV all relate to selectively replacing an amino acid in a protein with an analog of the amino acid (i.e., an amino acid with a modified side chain), wherein the amino acid analog does not replace other amino acids involved in protein function, such as lysine or cysteine. The amino acid analog is capable of further modification with a reporter molecule (i.e., label) following its incorporation into the protein at the desired site. Thus, Groups I-IV are related and should be considered together. The Examiner has not provided any evidence of separate status in the art, nor of a separate field of search.

In fact, by performing a complete search directed to Group IV, the Examiner is likely to have performed a search to the remaining of these groups, given that Groups I-IV are related. Therefore, it would appear that no undue burden of search would be placed on the Examiner, and that a co-extensive search would be virtually mandated.

At the very least, Applicants request that Groups I and IV be considered together. Group I relates to a protein, which is modified in that an amino acid other than cysteine or lysine has been replaced with an amino acid analog. Group IV relates to the process by which the protein can be used.

In response to the Examiner's requirement to elect a specific protein for Group IV, Applicants have selected a Tat protein. However, clearly the method of Group IV can employ any protein that has been modified by replacement of an amino acid with an amino acid analog at a site other than a lysine or cysteine residue. In view of this commonality, Applicants do not believe that restriction to a specific protein is proper.

Application No.: 09/972,016

Amendment and Response dated April 7, 2004 Reply to Office Action of March 11, 2004

Docket No.: 1368-9

Page 4

In response to the Examiner's requirement to elect a specific acceptor dye for Group IV, Applicants have selected a fluorophore, of which rhodamine is an example. As stated in the present application (at page 10, lines 20 and 21), while the acceptor dye molecule is usually a fluorophore, it does not have to be a fluorophore. Regardless of whether the acceptor dye is a fluorophore or other molecule, the disclosed commonality of operation, function or effect is that it is capable of accepting energy transferred to it from the donor dye molecule. Since applicants have disclosed this commonality among acceptor dye molecules (see page 10, lines 21-23, for e.g.), restriction to a particular acceptor dye molecule does not appear to be proper.

In view of the remarks above, Applicants respectfully request that the requirement for restriction be withdrawn and consideration of all of the claims on the merits be commenced.

Should the Examiner have any questions, the Examiner is respectfully invited to contact the undersigned agent at the telephone number set forth below.

Respectfully submitted,

Ylona H. Szakul

Gloria K. Szakiel

Registration No. 45,149 Agent for Applicant

HOFFMANN & BARON, LLP 6900 Jericho Turnpike Syosset, NY 11791 (973) 331-1700